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(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only. Not for subsequent breeding dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[67 FR 78972, Dec. 27, 2002, as amended at 69 FR 67818, Nov. 22, 2004]

§ 522.2483 Triamcinolone.

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams (mg) triamcinolone acetonide.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs and cats—(i) Amount—(A) Intramuscular or subcutaneous.* For inflammatory, arthritic, or allergic disorders, administer 0.05 to 0.1 mg per pound (lb) of body weight as a single injection. For dermatologic disorders, administer 0.1 mg per pound (lb) of body weight as a single injection. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.

(B) *Intralesional.* Administer 1.2 to 1.8 mg, divided in several injections around the lesion, spaced 0.5 to 2.5 centimeters apart, depending on lesion size. At any one site, the dose injected should not exceed 0.6 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.

(C) *Intra-articular and intrasynovial.* Administer 1 to 3 mg as a single injection, depending on the size of the joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 3 mg.

(ii) *Indications for use.* For the treatment of inflammation and related disorders, and the management and treatment of acute arthritis and allergic and dermatologic disorders.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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(2) *Horses—(i) Amount—(A) Intramuscular or subcutaneous.* Administer 0.01 to 0.02 mg/lb of body weight as a single injection. Usual dose is 12 to 20 mg.

(B) *Intra-articular and intrasynovial.* Administer 6 to 18 mg as a single injection, depending on the size of the joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 18 mg.

(ii) *Indications for use.* For the treatment of inflammation and related disorders.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 10167, Mar. 5, 2010]

§ 522.2582 Triflupromazine hydrochloride injection.

(a) *Specifications.* Triflupromazine hydrochloride injection contains 20 milligrams of triflupromazine hydrochloride in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs, cats, and horses to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.¹

(2) The drug is administered to dogs either intravenously at a dosage level of 0.5 to 1 milligram per pound of body weight daily, or intramuscularly at a dosage level of 1 to 2 milligrams per pound of body weight daily. It is administered to cats intramuscularly at a dosage level of 2 to 4 milligrams per pound of body weight daily. It is administered to horses intravenously or intramuscularly at a dosage level of 10 to 15 milligrams per 100 pounds of body weight daily to a maximum dose of 100 milligrams.¹

¹These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by § 514.111 of this chapter, but

(3) Not for use in horses intended for food.¹

(4) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.¹

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 522.2610 Trimethoprim and sulfadiazine.

(a) *Specifications.* Each milliliter (mL) contains:

(1) 40 milligrams (mg) trimethoprim suspended in a solution containing 200 mg sulfadiazine; or

(2) 80 mg trimethoprim suspended in a solution containing 400 mg sulfadiazine (as the sodium salt).

(b) *Sponsors.* See Nos. 000061 and 000856 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 1 mL of the product described in paragraph (a)(1) of this section (40 mg trimethoprim and 200 mg sulfadiazine) per 20 pounds (9 kilograms) of body weight per day by subcutaneous injection.

(ii) *Indications for use.* For the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to *Streptococcus zooepidemicus*.

(2) *Horses*—(i) *Amount.* 2 mL of the product described in paragraph (a)(2) of this section (160 mg trimethoprim and 800 mg sulfadiazine) per 100 pounds (45 kilograms) of body weight per day by intravenous injection as single, daily dose for 5 to 7 days. The daily dose may also be halved and given morning and evening.

(ii) *Indications for use.* For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, res-

piratory tract infections, acute urogenital infections, and wound infections and abscesses.

(iii) *Limitations.* Not for use in horses intended for human consumption.

[71 FR 30803, May 31, 2006]

§ 522.2615 Tripeleppamine hydrochloride injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 20 milligrams of tripeleppamine hydrochloride.

(b) *Sponsor.* See Nos. 053501 and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.741 of this chapter.

(d) *Conditions of use*—(1) *Amount*—(i) *Dogs, cats, and horses.* For intramuscular use only at a dose of 0.5 milligram per pound of body weight.

(ii) *Cattle.* Administer intravenously or intramuscularly at a dose of 0.5 milligram per pound of body weight.

(2) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(3) *Limitations.* Do not use in horses intended for food purposes. Treated cattle must not be slaughtered for food during treatment and for 4 days following the last treatment. Milk that has been taken during treatment and for 24 hours (two milkings) after the last treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[51 FR 44450, Dec. 10, 1986, as amended at 61 FR 29480, June 11, 1996; 62 FR 4164, Jan. 29, 1997]

§ 522.2630 Tulathromycin.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) tulathromycin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.745 of this chapter.

(d) *Conditions of use*—(1) *Beef and non-lactating dairy cattle*—(i) *Amount.* 2.5 mg per kilogram (/kg) body weight as a

¹ may require bioequivalency and safety information.